510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Home Skinovations Ltd.

HeatLux

JUL 6 2012

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Tavor building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name: HeatLux

Regulation Number: 21 CFR 890.5500

Regulation Name: Infrared lamp

Regulatory Class: Class II

Product Code: ILY

Predicate devices

- Quantum WARP10 Light Delivery system by Quantum Devices Inc. K032229.
- HVR Pain Relief Device by HVR LLC, K101716.
- Tanda Restore, by Pharos Life Corporation, K090008.
- LightStim, by LED Intellectual Properties LLC, K083580.

Intended use:

HeatLux is over the counter hand held device intended to emit energy in the visible and near IR spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local and blood circulation, and temporary relaxation of muscles.

Device Description& technology comparison to predicate device:

HeatLux is a hand held device battery operated that uses low power light spectrum, LED, at wavelength of 645 ±10 nm, combine with tip temperature stabilizer at 41^{0}C. The emitting optical power is in a uniform distribution with no hot spots.

Technology comparison of HeatLux with predicate devices:

	HeatLux	Quantum WARP10	HVR	Tanda Restore	LightStim
Wavelengths (nm)	645	650-950	650-950	870	630, 660,855, 940
Power mW/cm^2	60	50-80	50-80	60	50-80
Treatment area cm^2	7	10	10	27	37
Type of Energy source	LED	LED	LED	LED	LED
Targeted skin temperature ^{0}C	41±2	39-45	39-45	39-43	39-43
Recommended treatment time (minutes)	3-5				
Patient contacting material	Stainless steels 17-4PH, Rigid ABS	Rigid ABS	Rigid ABS	Rigid ABS	Rigid ABS

Performance data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21 CFR 1010.

Bench testing summary:

Bench testing preformed in order to verify the HeatLux performance to reach to the idle temperate of 41^{0}C and to maintain the temperature over time.

In the first test temperature sensor was attached to the metal surface of the device and monitors the temperature as function of time.

In the second setup a thermal camera was used in order to monitor the skin temperate and uniformity. The measurement was done on multiple body areas and skin types.

Substantial Equivalence:

The HeatLux is substantial equivalent to its predicate device. The data in this 510(k) submission demonstrate that the HeatLux device has compatible output as the predicate devices, and identical intended use. Therefore is substantial equivalent to its predicate devices.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the HeatLux should raise no new issues of safety or effectiveness.

June 21, 2012

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skinovations Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Home Skinovations Limited
% Dr. Amir Waldman
Vice President, Regulatory Affairs
Tavor Building POB 533
Yokneam Illit, Israel 20692

JUL 6 2012

Re: K120582
Trade/Device Name: HeatLux
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: June 21, 2012
Received: June 26, 2012

Dear Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K120582

Device Name HeatLux

Indications For Use:

HeatLux is over the counter hand held device intended to emit energy in the visible and near IR spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local and blood circulation, and temporary relaxation of muscles.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120582